CLAIMS

1. A transformed cell producing IgM of 100 mg/L or more.

2. A transformed cell producing IgM of 35 pg/cell/day or more.

3. The transformed cell of claim 1 or 2, which is a eukaryotic cell.

4. The transformed cell of claim 1 or 2, which is a prokaryotic cell.

5. The transformed cell of claim 3, which is a mammalian cell.

6. The transformed cell of any one of claims 1 to 5, which is an established cell line.

7. The transformed cell of claim 6, which is a non-lymphoid cell line.

8. The transformed cell of claim 7, which is a CHO cell line.

9. An expression vector comprising both (1) a nucleotide sequence encoding an IgM H chain and (2) a nucleotide sequence encoding an IgM L chain in the same vector, or a gene fragment comprising the genes (1) and (2).

10. An expression vector comprising (1) a nucleotide sequence encoding an IgM H chain, (2) a nucleotide sequence encoding an IgM L chain, and (3) a nucleotide sequence encoding an IgM J chain in the same vector, or a gene fragment comprising the genes (1), (2), and (3).

11. The expression vector or gene fragment of claim 9 or 10, wherein IgM secretion is controlled by a transcriptional regulatory sequence.

12. The expression vector or gene fragment of claim 11, wherein the transcriptional regulatory sequence is selected from the group consisting of:

- major late promoter of adenovirus 2;
- early promoter of simian virus 40;
- mouse mammary tumor virus (MMTV)-LTR promoter;
- thymidine kinase promoter of herpes simplex virus;
- cytomegalovirus promoter;

- polypeptide chain elongation factor 1 α promoter;
- bovine growth hormone promoter;
- β actin gene promoter; and
- CAG promoter.

13. The expression vector or gene fragment of claim 12, wherein the transcriptional regulatory sequence is selected from the group consisting of:
- early promoter of simian virus 40;
- cytomegalovirus promoter;
- polypeptide chain elongation factor 1 α promoter; and
- CAG promoter.

14. A transformed cell transformed by the vector or gene fragment of any one of claims 9 to 13.

15. The transformed cell of claim 14, which is selected from the transformed cell of any one of claims 1 to 8.

16. The transformed cell of claim 14 or 15, wherein the expression vector or gene fragment comprises a nucleotide sequence encoding a J chain.

17. The transformed cell of any one of claims 14 to 16, wherein the vector or gene fragment comprises a nucleotide sequence encoding an IgM J chain and the cell produces pentamer IgM with a content of 60% or more.

18. The transformed cell of claim 17, which produces pentamer IgM with a content of 80% or more.

19. The transformed cell of claim 14 or 15, wherein the vector or gene fragment comprises no nucleotide sequence encoding an IgM J chain and the cell produces hexamer IgM with a content of 50% or more.

20. The transformed cell of claim 19, which produces hexamer IgM with a content of 80% or more.

21. The transformed cell of any one of claims 14 to 16, wherein the vector or gene fragment

comprises a nucleotide sequence encoding an IgM J chain and the cell produces IgM for which the ratio of the produced pentamer and hexamer (pentamer/hexamer ratio) is 1.5 or more.

22. The transformed cell of claim 14 or 15, wherein the vector or gene fragment comprises no nucleotide sequence encoding an IgM J chain and the cell produces IgM for which the ratio of the produced hexamer and pentamer (hexamer/pentamer ratio) is 1.5 or more.

23. The transformed cell of claim 14 or 15, wherein the expression vector or gene fragment comprising a gene encoding IgM H and L chains comprises no nucleotide sequence encoding a J chain and the nucleotide sequence encoding the J chain has been expressively introduced by co-transfection.

24. A method for producing an IgM, comprising a step of culturing the cell of any one of claims 1 to 8 and 14 to 23 and then collecting the IgM.

25. A method for producing a substantially pure IgM, comprising a step of purifying an IgM from a culture supernatant obtained from culture of the cell of any one of claims 1 to 8 and 14 to 23.

26. An IgM obtained by the method of claim 24.

27. A substantially pure IgM obtained by the method of claim 25.

28. The IgM of claim 26 or 27, which is a human, mouse, human chimeric, or humanized antibody.

29. The IgM of any one of claims 26 to 28, which is a substantially pure pentamer or hexamer.

30. A substantially pure pentamer or hexamer IgM comprising a sugar chain added by a CHO cell.

31. The IgM of any one of claims 26 to 30, which is an anti-sugar chain antibody.

32. The IgM of claim 31, which is an anti-ganglioside antibody.

33. The IgM of claim 32, which is an anti-GM2 or GM3 antibody.

34. An isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 or a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2.

35. An isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 3 or a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 4.

36. An isolated protein comprising an amino acid sequence encoded by the polynucleotide of claim 34.

37. An isolated protein comprising an amino acid sequence encoded by the polynucleotide of claim 35.

38. An IgM comprising the protein of claim 36 and the protein of claim 37 as constituent units.

39. The IgM of claim 38, further comprising an IgM J chain.

40. The IgM of claim 39, which is a pentamer.

41. An isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 19 or a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 20.

42. An isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 21 or a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 22.

43. An isolated protein comprising an amino acid sequence encoded by the polynucleotide of claim 41.

44. An isolated protein comprising an amino acid sequence encoded by the polynucleotide of claim 42.

45. An IgM comprising the protein of claim 43 and the protein of claim 44 as constituent units.

46. The IgM of claim 45, further comprising an IgM J chain.

47. The IgM of claim 46, which is a pentamer.

48. A pharmaceutical composition comprising the IgM of any one of claims 26 to 33, 38, and 45.

49. A pharmaceutical composition comprising 80% or more pentamer IgM.

50. A pharmaceutical composition comprising 50% or more hexamer IgM.

51. The pharmaceutical composition of claim 50, comprising 80% or more hexamer IgM.

52. A pharmaceutical composition comprising an IgM for which pentamer/hexamer ratio is 1.5 or more.

53. A pharmaceutical composition comprising an IgM for which hexamer/pentamer ratio is 1.5 or more.

54. A method for analyzing an IgM polymer, comprising a step of separating an IgM by SDS-polyacrylamide gel electrophoresis using as a carrier polyacrylamide gel satisfying at least one condition selected from the group consisting of:

a) a polyacrylamide gel polymerized at a high temperature;

b) a polyacrylamide gel containing a high concentration of ammonium persulfate and glycerol; and

c) a polyacrylamide gel homogenized by stirring and degassed prior to polymerization.

55. The method of claim 54, wherein the temperature in condition a) is 37°C or higher.

56. The method of claim 54, wherein the concentration of ammonium persulfate in condition b) is 0.25% or more.

57. The method of claim 54, wherein the polyacrylamide gel satisfies at lease two conditions selected from the group consisting of conditions a) to c).

58. The method of claim 54, wherein the polyacrylamide gel satisfies all the conditions a) to c).

59. The method of claim 54, wherein a buffer for electrophoresis is a Tris-acetate SDS electrophoresis buffer.

60. The method of claim 54, wherein the IgM polymer is an IgM pentamer and/or hexamer.

61. The method of claim 54, wherein the method comprises analyzing an IgM aggregate.

62. The method of claim 54, wherein the method is free from use of RI.

63. The method of claim 54, comprising a step of quantifying the IgM polymer separated after electrophoresis.

64. An electrophoresis gel for separating an IgM polymer by SDS-polyacrylamide gel electrophoresis, comprising a polyacrylamide gel satisfying at least one condition selected from the group consisting of:

a) a polyacrylamide gel polymerized at a high temperature;

b) a polyacrylamide gel containing a high concentration of ammonium persulfate and glycerol; and

c) a polyacrylamide gel homogenized by stirring and degassed prior to polymerization.

65. A method for producing an electrophoresis gel for separating an IgM polymer by SDS-polyacrylamide gel electrophoresis, comprising at least one step selected from the group consisting of:

a) polymerizing an acrylamide at a high temperature;

b) adding a high concentration of ammonium persulfate to an acrylamide, and

c) homogenizing an acrylamide by stirring and degassed prior to polymerization.